

MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068

Phone: (973) 228-9898 - Fax: (973) 228-0303

www.mazieslater.com

David A. Mazie*
Adam M. Slater*^o
Eric D. Katz*^o
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn^o
David M. Estes

*Certified by the Supreme Court of
New Jersey as a Civil Trial Attorney

^oMember of N.J. & N.Y. Bars

Karen G. Kelsen^o
Cheryll A. Calderon
Adam M. Epstein^o
Cory J. Rothbort*^o
Michael R. Griffith^o
Christopher J. Geddis
Alexander Q. Reynoso
Samuel G. Wildman
Julia S. Slater^o

February 11, 2021

VIA CM/ECF

Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter summarizing the issues in advance of the upcoming
February 12, 2021 status conference.

1. Update on Defendants' Deposition Schedules

The Parties continue to meet and confer on the schedule of Defendants' depositions in light
of the sixty-day extension granted last week.

2. Third-Party Subpoena Briefing

The Parties have fully briefed this issue.

3. ZHP's Motion to Seal

ZHP and its subsidiaries, like nearly all defendants in this case, have egregiously over
designated their documents as confidential in violation of the Court's Confidentiality and

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 2

Protective Order and the Court's subsequent decision on Torrent's confidentiality designations. (ECF 139, Ex. A hereto). *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, No. 19-md-2875, 2021 WL 75258 (D.N.J. Jan. 8, 2021) (Ex. B hereto). The over-designation of documents as confidential and subject to the Protective Order is a significant problem in this litigation, as recognized by Judge Schneider in his Torrent decision. The first and most significant issue is that documents in a litigation are presumed to be public, and the Defendants' over-designation is an improper tool to shield the truth from the public, which is especially problematic in a case of this nature which is focused on public health issues. The burdens are also significant; for example, this creates significant extra work for the Plaintiffs in filing papers with the Court, requiring multiple cumbersome filings and triggering a meet and confer process and further motion practice regarding whether the documents must be made public. In addition, this burdens the use Plaintiffs can make of the documents, including at depositions, and to the extent Plaintiffs wish to discuss the documents or disclose the documents to/with others. During its meet and confer process, ZHP only agreed to de-designate obviously public documents, such as legal complaints. On February 10, 2021, it then filed a motion to seal the remaining documents, many of which were attached to papers filed as far back as November 2020. According to the Court's motion calendar, Plaintiffs' opposition is due on March 1, 2021. (<https://www.njd.uscourts.gov/sites/njd/files/2021MotionCal.pdf>). Plaintiffs seek to confirm this due date.

4. ZHP's Motion for a Protective Order

The Parties have fully briefed this issue.

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 3

5. Service of Losartan and Irbesartan Complaints

The Master Complaints for losartan and irbesartan are now on file, and Plaintiffs have sent waivers of service to each Defendant. Nearly all defendants listed in the losartan and irbesartan Master Complaints were also included in the valsartan Master Complaints and are therefore already represented by counsel. To date, very few of them have returned the waivers of service. Plaintiffs do not wish to prolong this process.

For any domestic defendant who is already represented by counsel and receiving notifications in this MDL via ECF, Plaintiffs request that the Court require these defendants to waive service. Some defendants expressed concern about having to file an answer if they waived service now. Plaintiffs have informed them that they are willing to allow Defendants to file answers on whatever schedule the Court deems appropriate.

Plaintiffs have also sent waivers of service to the remaining domestic defendants and will update the Court on the status of service at the next discovery conference.

Next, there are a small number of foreign defendants who are located outside of the United States and who are not part of the valsartan case. For these defendants, Plaintiffs ask that the Court extend its May 7, 2019 order that required Plaintiffs only to serve these defendants through the Hague once with a single complaint. (ECF 99, Ex. C).

Finally, there are certain defendants who are part of the losartan and irbesartan master pleadings but who (as far as plaintiffs are aware) have not yet been sued in an individual case. Plaintiffs have also been unable to identify who represents them and thus have been unable to send waivers of service. Plaintiffs therefore request that the Court issue summonses for the Master

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 4

Complaints for the following defendants so Plaintiffs can serve these defendants and ensure their interests are represented at upcoming hearings:

- Vivmed Life Sciences pvt Ltd
- Westminster Pharmaceuticals

Plaintiffs also note that Torrent filed a joint stipulation regarding the dismissal of Torrent Private and the acceptance of service of Torrent Pharmaceuticals for valsartan, losartan, and irbesartan cases on November 13, 2020. (ECF 630, Ex. D hereto). Plaintiffs respectfully ask the Court to approve this joint stipulation.

6. Defendants' Inadequate Privilege Logs

Defendants' privilege logs do not provide the information necessary for Plaintiffs and the Court to assess the propriety of their privilege designations, and thus prevent meaningful discussion between the parties. (Exs. E-J hereto).¹ First, Plaintiffs need a "cast of characters" listing the name, title, department, and email address of each person named in the privilege log. This is obviously critical foundational information in order to know who was involved in the subject communications and to weigh the claim of privilege against the reality that even if an attorney is on a document, most or all of the communication is often business related and not the provision of or request for privileged legal advice. Hetero has agreed to provide this "cast of characters," and Plaintiffs are hopeful that the other Defendants will also agree to do so. If not, Plaintiffs request entry of an Order compelling production of this information.

¹ The privilege logs contain over twenty columns. In order to focus the Court's attention on the issues raised and to file the document on ECF in a readable format, Plaintiffs have removed the columns from the attached privilege logs that do not reflect the senders, authors, or recipients of the documents or the description of the documents themselves.

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 5

Second, Defendants' descriptions of their allegedly privileged document are also grossly inadequate. The assertion of privilege is disfavored and should be applied in the narrowest fashion possible. In order for the opposing party and the Court to be able to assess the assertion of privilege, the party asserting the privilege must provide the opposing party and ultimately the Court with, among other things, **"a specific explanation of why each document is privileged or immune from discovery," which "must include a comprehensive presentation of all factual grounds and legal analyses in a non-conclusory fashion."** *Pippenger v. Gruppe*, 883 F. Supp. 1201, 1212 (S.D. Ind. 1994); *see also Chao v. Koresko*, Nos. 04-3614, 05-1440, 05-1946, 05-2673, 2005 WL 2521886, at *4 (3d Cir. Oct. 12, 2005) (Ex. L hereto); *Wachtel v. Health Net, Inc.*, 239 F.R.D. 81, 106 (D.N.J. 2006).

Moreover, "[b]ecause the attorney-client privilege obstructs the truth-finding process, it is construed narrowly." *Westinghouse Elec. Corp. v. Republic of Philippines*, 951 F.2d 1414, 1423 (3d Cir. 1991). Thus, "not all communications between a client and lawyer are privileged. The attorney client privilege only insulates communications that assist the attorney to formulate and render legal advice." *Peterson v. Bernardi*, 262 F.R.D. 424, 428 (D.N.J. 2009) (citing *Westinghouse*, 951 F.2d at 1424). This Court has explained:

The privilege does not apply simply because a statement was made by or to an attorney. *HPD Laboratories, Inc. v. Clorox Company*, 202 F.R.D. 410, 414 (D.N.J. 2001). Nor does the privilege attach "simply because a statement conveys advice that is legal in nature." *Id.* The attorney client privilege only applies to disclosures necessary to obtain informed legal advice which might not have been made absent the privilege. *Id.* (citations omitted).

Peterson, 262 F.R.D. at 428. A privilege log must allow the opposing party and the court to assess whether the withheld documents meet this standard. *Id.* Simply listing an attorney as an author

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 6

or recipient does not satisfy a defendant's obligation to justify its invocation of a privilege. *Id.* Instead, the privilege log must identify the attorney and client involved in the attorney-client relationship. *In re Asousa P'ship*, No. 01-12295DWS, 2005 WL 3299823, at *2 (Bankr. E.D. Pa. Nov. 17, 2005) (finding that "[w]hile the privilege log describes this as a 'communication relating to legal strategy,' it fails to identify Steven King as its counsel or Smithfield as a recipient," and so holding "I cannot therefore find an attorney-client communication subject to the privilege") (Ex. M hereto). The withholding party must then explain in a non-conclusory manner how the document contains information necessary to obtain or render legal advice. *Peterson*, 262 F.R.D. at 428. Merely describing a topic as "legal" does not satisfy this requirement. *Id.* "Where . . . a corporation seeks to protect communication to or from an attorney who serves the corporation in both a legal and business capacity, the corporation must clearly demonstrate that the communication to be protected was given in the attorney's legal capacity." *Id.* at *2. For example, "[i]ncluding an attorney on the distribution list of an interoffice memo, Cc'ing numerous people who are ancillary to the discussion, one of whom happens to be an attorney, or forwarding an e-mail several times until it reaches an attorney does not amount to 'attorney client communication.'" *In re Gabapentin Patent Litig.*, 214 F.R.D. 178, 186 (D.N.J. 2003).

Moreover, documents containing non-privileged information should be produced with the limited privileged information redacted. This is a significant issue here, where long email chains and extensive documents appear to be withheld in their entirety, despite the fact that only a small portion is even subject to the privilege assertion. *See, e.g., McKee v. PetSmart, Inc.*, 71 F. Supp. 3d 439, 443 (D. Del. 2014) (holding that "to the extent that the PowerPoint presentation may constitute a combination of facts, which are discoverable, and legal conclusions regarding those

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 7

facts, which are not discoverable, defendant should produce a redacted version of the PowerPoint presentation to plaintiffs."); *Benefitvision Inc. v. Gentiva Health Servs., Inc.*, No. CV 09–473, 2011 WL 3796324, at *2 (E.D.N.Y. May 23, 2011) (holding that "[i]f there are e-mail chains in which Defendants claim privilege over only parts of the e-mail chain, those allegedly privileged e-mails must be redacted and all non-privileged portions must be produced.") (Ex. N hereto); *S.E.C., Inc v. Wylly*, No. 10 Civ. 5760, 2011 WL 3851129, at *5 (S.D.N.Y. June 17, 2011) (same) (Ex. O hereto).

When a party has failed to comply with this rule, courts have ordered the party to amend their privilege logs “to allow either plaintiffs or [the c]ourt to evaluate what, if any, claims of privilege [the defendant] may have.” *Wultz v. Bank of China Ltd.*, 979 F. Supp. 2d 479, 497 (S.D.N.Y. 2013). After having this opportunity to amend and failing to comply with the court’s order, courts have held that the party “will have waived any claims of privilege over those documents.” *Id.*; *see also Chao*, 2005 WL 2521886, at *4. The “large volume” and “foreign” or “challenging” nature of the relevant discovery will not excuse compliance with these requirements. *Id.*

The following are examples from the privilege logs provided by the Manufacturer Defendants:

- ZHP: “Email requesting legal advice regarding regulatory issues.” (Ex. E hereto).
- Hetero: “Draft submission containing counsel’s legal advice concerning FDA compliance.” (Ex. F hereto).
- Teva: “Document reflecting legal advice regarding marketing issues.” (Ex. G hereto).

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 8

- Torrent: “Draft letter prepared by counsel regarding manufacturing issues.” (Ex. H hereto).
- Mylan: “Document requesting legal advice regarding regulatory issues.” (Ex. I hereto).
- Aurobindo: “Document reflecting legal advice regarding regulatory issues and litigation communications.” (Ex. J hereto).

Federal Rule of Civil Procedure 26(b)(5) and the Court’s ESI Order do not permit such conclusory descriptions. (ECF 127, Ex. K hereto)

Plaintiffs need more specific descriptions of the documents in order to assess which documents to challenge. Obviously, these descriptions would not include the substantive legal advice, but the nature of the factual and legal discussion is vital to assessing the invocation of the privilege. *Pippenger*, 883 F. Supp. at 1212; *see also Chao*, 2005 WL 2521886, at *4; *Wachtel*, 239 F.R.D. at 106. For example, does the entire document reflect outside counsel’s advice to the vice president of regulatory affairs and quality assurance regarding what the Federal Food, Drug, and Cosmetic Act and its implementing regulations required the defendant to submit to the FDA after initially discovering the carcinogenic impurity N-Nitrosodimethylamine in its valsartan API? Without such a description, Plaintiffs must blindly challenge documents with the hope of randomly picking the right ones for the Court to review and ultimately release. This would waste the Parties’ and the Court’s time, and it would also violate the Federal Rules of Civil Procedure and the ESI Order in this case. Vague descriptions obstruct the truth finding process.

The law cited herein requires Defendants to move very quickly to fix the extensive deficiencies, provide far more specific and informative descriptions of the subject matter of the

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 9

documents and the specific basis for the privilege claim – while withdrawing the privilege claims to the extent not narrowly focused only on the parts of the documents subject to their argument for privilege. This is not something the Defendants can be provided extensive time for, as this issue has been discussed for weeks and Defendants have been on notice of their obligations from the outset based on the clear legal standards they were always subject to. Due to the still compressed schedule, this needs to happen immediately.

Based on the foregoing, and the ordinary practice, the amended privilege logs and casts of characters **must** be provided immediately by Defendants in order to facilitate meaningful document-by-document privilege log challenges by Plaintiffs. In this vein, Plaintiffs have initiated these challenges, consistent with Paragraph 4 of Special Master Order No. 2 (ECF 843) entered on February 4, 2021, which provides that, by February 15, 2021, “Plaintiffs shall identify any privilege log that Plaintiffs contend is inadequate and the reasons for the claimed inadequacy.”

7. ZHP’s Discovery Deficiencies

On February 10, 2021, Plaintiffs documented a number of discovery deficiencies, primarily related to the document production, in a letter to ZHP. (Ex. P hereto). Plaintiffs intend to meet and confer with ZHP to address these deficiencies before the February 24, 2021 case management conference. If ZHP has not agreed to address the discovery deficiencies by that time, Plaintiffs will bring them to the Court for resolution.

8. Hetero’s Discovery Deficiencies

On February 5, 2021, Plaintiffs sent a letter to Hetero cataloguing deficiencies in Hetero’s document production and providing a revised deposition schedule in the wake of the Court’s decision to grant a sixty-day extension of discovery. (Ex. Q hereto).

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 10

Hetero responded to Plaintiffs via letter on February 9, 2021, denying that many of the issues that Plaintiffs raised existed. (Ex. R hereto). Hetero indicated that seven of the custodial files Plaintiffs could not find in the production were in fact produced - despite not being listed properly as having been produced in Hetero's Production Index - and two of the remaining three custodial files were not produced **because they did not have email addresses**. Hetero also contended that they were not under an obligation to produce the custodial file of the Analys Labs employee, B.V. Ramireddy because he is employed by a third party and they do not have control over his documents. Hetero also indicated that they would look into the alleged metadata deficiencies Plaintiffs cited and agreed to produce a "cast of characters" in connection with the Privilege Log as requested by Plaintiffs.

On February 10, 2021, the Plaintiffs and Hetero engaged in a lengthy conference call to talk through the issues raised by the Plaintiffs.² Hetero initially pushed back on Plaintiffs' identification of production deficiencies, but as the call continued, it was apparent that Hetero came to understand that its productions have significant, material deficiencies, many due to blatant non-compliance with multiple orders and the ESI Protocol. This was apparently unknown to or not understood by Hetero.

The first issue to address is Hetero's apparent failure to produce the ten custodial files identified by Plaintiffs. Hetero represented that the custodial files had been produced; however, if

² Hetero argued during the meet and confer that Plaintiffs should have raised these issues earlier. In fact, Plaintiffs continually raised perceived deficiencies in the productions in 2020, but Judge Schneider accepted Defendants' response that they were complying and all documents would be produced on an evenly spaced rolling basis and completed in November 2020. Therefore, Plaintiffs had to wait until after the massive November 2020 document dumps to review the majority of the documents and these issues were only crystallized recently through this process.

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 11

that is so, it was established during the call that the manner of the production “hid” the ESI data needed to identify, collect, and search the custodial documents, so they can be used in depositions and with experts. Specifically: (1) Hetero’s Production Index violates the ESI Protocol because the entries did not consistently identify the **particular custodians and the bates ranges** of their custodial documents produced, in particular for the final production in November 2020, when Hetero produced the large majority of its custodial documents. Pursuant to Section III, Paragraph I of the Electronic Discovery Protocol, “Each production also contain a Production Index, which shall be updated with each production, setting forth (1) dates, (2) Bates number range, (3) source(s) (e.g., custodians, database) of the materials contained in each production volume, (4) whether the production was a replacement production, and (5) the date of withdrawal of protected designation and replacement with no protected designation for applicable Bates ranges, if applicable.” (ECF 127, Ex. K hereto). Plaintiffs had noted in their letter that Hetero’s most recent Production Index, dated November 30, 2020, inadequately stated, “Completed custodial document productions for all custodians” for Bates numbers HLL00478112-HLL1234918, rather than providing the specificity needed to easily understand what was produced, and which custodians and key topics they related to. Second, in violation of the ESI Protocol (ECF 127, Ex. K hereto), Hetero’s **metadata field for “Custodian”** is not in the proper format (LASTNAME, FIRSTNAME, MIDDLENAME), which makes it incredibly difficult, if not impossible, for custodians to be reliably searched and located. Instead, vague and inconsistent references are provided for a large number of documents, preventing Plaintiffs from knowing the source of the document, and the context of its preparation and use. Additional deficiencies in the metadata, including **missing fields such as Author and Duplicate Custodian, as well as clearly inaccurate Created and**

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 12

Modified dates (i.e., “12/31/9999”), have also been identified. This has heavily burdened Plaintiffs’ review and preparation for depositions, and literally made it impossible for Plaintiffs to confirm that these productions have been made.

Unfortunately, it became clear during the call that Hetero did not have a good understanding of its obligations per the ESI Protocol, and Hetero’s counsel indicated that they needed to reach out to their vendor and get back to Plaintiffs with a timeframe for production of replacement files with compliant metadata. At this juncture of the litigation, these deficiencies must be remedied immediately – extended deadlines will greatly prejudice Plaintiffs.

In addition to Hetero’s extensive violations of the ESI Protocol, Hetero did not make compliant custodial productions for Rajesh Khanna S and Suresh Reddy Boddapati because of yet another fundamental misunderstanding by Hetero of its obligations. Hetero’s counsel asserted that no custodial productions were required because they claimed these two employees did not have Hetero company-associated email addresses. In fact, Plaintiffs identified an email address for Rajesh Khanna that was located in a document found in the production (from another witness’s files apparently), and there were emails produced in the production that were both received and sent by Rajesh Khanna. Additionally, even in the extremely unlikely event that these employees did not have work emails, their custodial productions were required to be made from any **and all emails they may have used for work purposes including personal emails**. Plaintiffs asked what investigation was done to determine whether these custodians had an email address or communicated via a personal email address, and defense counsel was unable to describe any investigation. In addition, **Hetero’s counsel was inexplicably surprised to learn that the ESI Protocol also required the production of custodial hard copy documents, with metadata.**

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 13

Hetero incredibly conceded that all hard copy custodial files were produced (to the extent collected – which is a big question) as part of general corporate productions without any demarcation, with the Custodian field incorrectly indicating “Hetero.” In this connection, Hetero also admitted that documents the company had in its possession from its third-party testing vendor Analys Labs were also produced under the Custodian “Hetero,” and Hetero was unable to tell Plaintiffs when the production of documents from Analys Labs – in response to the subpoena served on Analys Labs per the parties’ agreement – would be completed. Not surprisingly, the “Custodian” listed simply as “Hetero” has almost 28,000 documents under that designation. These tactics, whether deliberate or due to inexperience, accomplish the same thing – hiding and obscuring documents from Plaintiffs’ reviewers, making it impossible to know the source and context of documents, and severely obstructing the document review and deposition preparation – all as the clock ticks. In fact, until now Hetero has paid mere lip service to cooperating with Plaintiffs while doing nothing to answer legitimate questions. Plaintiffs hope that Hetero has moved past a blanket policy of denial in order to fulfill its obligations to cooperate and facilitate discovery.

All of these deficiencies need to be remedied immediately, including reproduction of documents, with proper indexes and metadata, accurately and completely providing the information required by the ESI Protocol and basic custom in a proceeding of this nature.

The second issue to address is Hetero’s deficient privilege log. (Ex. F hetero). Hetero has agreed to produce a “cast of characters” named in the Privilege Log, including their name, position, department, and email address(es); thus, that issue need not be argued with regard to Hetero, and can be documented in the Order.

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 14

Plaintiffs also pointed to the inadequate descriptions of the substance of the documents and the basis for the claim of privilege, to enable a substantive discussion regarding the claim of privilege. Section V, Paragraph A of the Electronic Discovery Protocol requires the producing party to provide an updated summary log with each production, identifying any information withheld or redacted based on the assertion of privilege, in an electronically searchable format (e.g., Excel), containing, for each document claimed as privileged, a description of "the nature of the documents, communications, or tangible things not produced or disclosed - **and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim,**" pursuant to Fed. R. Civ. P. 26(b)(5)(A).

For example, there are over forty separate entries that state the same "Description" as the basis for the privilege designation: "Attachment provided at the request of counsel in connection with pending litigation requesting and providing information to facilitate the rendition of legal advice regarding discovery requests in Cain-Ament matter." There are also over 35 entries that simply list "Draft submission containing counsel's legal advice regarding FDA inspection report" as the basis for the privilege designation. (Ex. F hereto). These entries are illustrative of the lack of information provided due to vague, uninformative descriptions, which will make it impossible for the parties to resolve privilege claims without the Court's in camera review of every document, which will be cumbersome to say the least. Hetero should be compelled to provide the information needed for the Plaintiffs to understand and evaluate privilege claims, determine whether parts of a document are clearly not subject to a privilege claim and should be produced regardless of other redactions, and enter into a meaningful dialogue in the face of the impending depositions.

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 15

Plaintiffs additionally raised the issue of documents that Plaintiffs were unable to locate in the production due to non-production or the manner in which they were produced. These many documents include such things as SOPs, SOP indexes, the versions of the critical Quality Manual that were in effect when Hetero was ignoring Quality standards and contaminating valsartan with nitrosamines including NDMA, and many other documents that were listed for Hetero. (Ex. Q hereto). Plaintiffs request a very short deadline for the Hetero productions to be brought into compliance, and direction that Hetero meet and confer in a cooperative, good faith manner.

9. Aurobindo's Discovery Deficiencies

To date, Aurobindo's document production is dwarfed by those of any other defendant. Aurobindo has only produced 13,059 documents. Of those, only 633 came from Aurobindo Pharma, Ltd., the entity responsible for the manufacture of the API. For reference, ZHP produced 244,481 documents, and Mylan produced 235,944.³

According to Aurobindo's internal analyses, the source of contamination of its VCDs was the recovered solvent it purchased from Lantech. It is therefore deeply concerning that Plaintiffs have only received 98 documents that even mention Lantech. Plaintiffs have asked counsel for Aurobindo on numerous occasions why so few documents have been produced. Plaintiffs and Aurobindo have met and conferred twice this week regarding this issue, and at Plaintiffs' request, Aurobindo has agreed to do the following:

- 1) Provide Plaintiffs with the total number of non-duplicative documents that resulted from running the search terms over all custodial files;

³ These numbers were calculated based upon documents with the prefixes "ZHP" and "MYLAN-MDL2875."

Hon. Robert B. Kugler, U.S.D.J.
Hon. Thomas I. Vanaskie, Special Master
February 11, 2021
Page 16

- 2) Verify that all non-custodial documents from Aurobindo Pharma Ltd. that are responsive to Plaintiffs' Rule 34 requests have been produced; and
- 3) Verify that all responsive SOPs have been produced, including those most closely related to the sourcing, purchase, use, quality, etc. relating to recovered solvents, and specifically those purchased from Lantech.

The parties are also continuing to meet and confer as to certain custodians from Aurobindo Pharma, Ltd., and if they are unable to come to an agreement, Plaintiffs intend to make these issues ripe for the CMC in two weeks' time.

Finally, the parties are planning to touch base on these issues prior to the conference tomorrow and may have additional updates for the Court at that time.

10. Wholesaler's T3/DSCA Issue

The Parties have continued to meet and confer and expect to resolve the one remaining item within a week; thus, there will be no need for briefing on the matter.

11. Updated Short Form Complaints

On January 29, 2021, Plaintiffs submitted an updated Short Form Complaint and implementing order (titled 13B so that it will be easy for other attorneys to locate). (ECF No. 815). Plaintiffs request that the implementing order for the updated Short Form Complaint be entered.

Respectfully,



ADAM M. SLATER

cc: All Counsel (via CM/ECF)